

## § 486.1

- 486.308 Designation of one OPO for each service area.  
486.309 Re-certification from August 1, 2006 through July 31, 2010.  
486.310 Changes in control or ownership or service area.

### Re-certification and De-certification

- 486.312 De-certification.  
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### ORGAN PROCUREMENT ORGANIZATION OUTCOME REQUIREMENTS

- 486.318 Condition: Outcome measures.

### ORGAN PROCUREMENT ORGANIZATION PROCESS PERFORMANCE MEASURES

- 486.320 Condition: Participation in Organ Procurement and Transplantation Network.  
486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks.  
486.324 Condition: Administration and governing body.  
486.326 Condition: Human resources.  
486.328 Condition: Reporting of data.  
486.330 Condition: Information management.  
486.342 Condition: Requesting consent.  
486.344 Condition: Evaluation and management of potential donors and organ placement and recovery.  
486.346 Condition: Organ preparation and transport.  
486.348 Condition: Quality assessment and performance improvement (QAPI).

AUTHORITY: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b-8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C. 273).

## Subpart A—General Provisions

### § 486.1 Basis and scope.

(a) *Statutory basis.* This part is based on the following sections of the Act:

1102 and 1138(b), 1871 of the Social Security Act, section 371(b) of the Public Health Service Act—for coverage of organ procurement services.

1861(p)—for coverage of outpatient physical therapy services furnished by physical therapists in independent practice.

1861(s) (3), (15), and (17)—for coverage of portable X-ray services.

(b) *Scope.* (1) This part sets forth the conditions for coverage of certain specialized services that are furnished by suppliers and that are not specified in other portions of this chapter.

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(2) The conditions for coverage of other specialized services furnished by suppliers are set forth in the following regulations which, unless otherwise indicated, are part of this chapter:

(i) Ambulatory surgical center (ASC) services—Part 416.

(ii) Ambulance services—Part 410, subpart B.

(iii) ESRD services—Part 405, subpart U.

(iv) Laboratory services—Part 493.

(v) Mammography services—Part 410, subpart B (§ 410.34) and 21 CFR Part 900, subpart B, of the Food and Drug Administration regulations.

(vi) Rural health clinic and Federally qualified health center services—Part 491, subpart A.

[60 FR 50447, Sept. 29, 1995, as amended at 71 FR 31046, May 31, 2006]

## Subpart B [Reserved]

## Subpart C—Conditions for Coverage: Portable X-Ray Services

AUTHORITY: Secs. 1102, 1861(s) (3), (11) and (12), 1864, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x(s) (3), (11), and (12), 1395aa and 1395hh).

SOURCE: 34 FR 388, Jan. 10, 1969, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977, and further redesignated and amended at 60 FR 2326, Jan. 9, 1995.

### § 486.100 Condition for coverage: Compliance with Federal, State, and local laws and regulations.

The supplier of portable X-ray services is in conformity with all applicable Federal, State, and local laws and regulations.

(a) *Standard—licensure or registration of supplier.* In any State in which State or applicable local law provides for the licensure or registration of suppliers of X-ray services, the supplier is (1) licensed or registered pursuant to such law, or (2) approved by the agency of the State or locality responsible for licensure or registration as meeting the standards established for such licensure or registration.

(b) *Standard—licensure or registration of personnel.* All personnel engaged in operating portable X-ray equipment